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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,493	12/15/2003	Kenneth P. Reever	BSCU-134/01US 027060-2723	3812

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COOLEY GODWARD KRONISH LLP
ATTN: Patent Group
Suite 1100
777 - 6th Street, NW
WASHINGTON, DC 20001

EXAMINER	
BLANCO, JAVIER G	

ART UNIT	PAPER NUMBER
3774	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/736,493	REEVER, KENNETH P.	
	Examiner	Art Unit	
	JAVIER G. BLANCO	3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,9-12,14,15 and 19-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7, 9-12, 14, 15, and 19-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/17/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 17, 2008 has been entered.

Response to Amendment

2. Applicant's amendment of claims 7, 12, and 15 in the reply filed on February 14, 2008 is acknowledged.

3. Applicant's addition of claims 19-30 in the reply filed on February 14, 2008 is acknowledged.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 7, 9-11, 14, and 15 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Cioanta et al. (US 6,682,555 B2).

Referring to Figures 1A, 6A-6D, 8, 10B-10E, and 11, Cioanta et al. disclose a prostatic stent (20 and/or 75) comprising:

(i) A first segment (20 + 75, or 52 + 15 + 22) including an external surface, and internal surface, a proximal portion, a distal end, a lumen (see Figures 6A-6D) defined by the internal surface and extending within the first segment, and a plurality of openings (through openings 85 and/or 80), the proximal portion including at least one opening (20a, 20e) in communication with the lumen;

(ii) A second segment (distal section of 21) including an external surface, and internal surface, a proximal end, a distal end, a lumen (see Figures 6A-6D) defined by the internal surface and extending within the second segment;

(iii) A connecting segment (proximal section of 21, which is locatable in the sphincter) disposed between the first and second segments and coupling together the first and second segments, wherein the connecting element is solid (i.e., not liquid or gaseous); and

(iv) An anticoagulant (e.g., pentosan polysulfate) is disposed on the internal surfaces of the first segment and the second segment (see column 15, line 29 to column 16, line 50). The external surfaces of the segments comprise a polymerizable agent, including a hemostatic agent (see column 15, line 58 to column 16, line 19).

6. Claims 7, 9-12, 14, 15, and 19-30 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Datta et al. (US 6,338,739 B1) in view of Donovan et al. (5,833,651 A; cited in Applicant's IDS), Alt et al. (US 5,788,979; cited in Applicant's IDS), or Jernberg (US 5,290,271 A).

Referring to Figures 3, 4, 8, 10-15, and 18, Datta et al. disclose a prostatic stent comprising:

(i) A first segment (e.g., section 50) including an external surface, and internal surface, a proximal portion, a distal end, a lumen (passageway 51 of passageway 11 of stent 10) defined by the internal surface and extending within the first segment, and a plurality of openings **(first interpretation:** pores created by degradation of the prostatic stent; **second interpretation:** Figures 13 and 14, openings 590; **third interpretation:** Figure 15, hollow passageway 830 of fiber 800), the proximal portion including at least one opening (Figure 4: proximal opening on proximal end) in communication with the lumen;

(ii) A second segment (e.g., section 30) including an external surface, and internal surface, a proximal end, a distal end, a lumen defined by the internal surface and extending within the second segment;

(iii) A connecting segment (e.g., connecting segment 60) disposed between the first and second segments and coupling together the first and second segments, wherein the connecting segment comprises a coated (Figure 4: outer layer/covering 130) solid wire/core 110. Datta et al. further disclose the fiber/wire as either solid or hollow (see column 7, lines 52-60).

As disclosed in column 12 at lines 8-48, the prostatic stent will comprise therapeutic agents/drugs, which agents/drugs will include (without limitation) agents/drugs well known in the art. The external surface of the segments will comprise a polymeric matrix including a drug/agent. The internal surface of the segments will comprise a polymeric matrix including a drug/agent. The choice of a particular drug/agent combination will inherently be left to one skilled in the art depending on the intended purpose (i.e., dependent on patient's particular condition).

Donovan et al. disclose a stent (see column 13, lines 66-67; column 14, lines 1-9) comprising a hemostatic agent (i.e., fibrin) on the external surface of the stent (see column 5, lines 61-67; column 8, lines 13-17) and an anticoagulant (i.e., heparin) on the internal surface (e.g., lumen-exposed surface) of the stent (see column 15, lines 15-26) in order to enable different beneficial actions to occur at different surfaces of the stent. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of a stent comprising a hemostatic agent on the external surface of the stent and an anticoagulant on the internal surface of the stent, as taught by Donovan et al., with the stent of Datta et al., in order to enable different beneficial actions to occur at different surfaces of the stent.

Alt et al. disclose a stent comprising a polymerizable hemostatic agent on an external surface, and an anticoagulant on an internal surface (see column 6, lines 8-13; see Examples) in order to enable different beneficial actions to occur at different surfaces of the stent (see column 6, lines 5-16). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of a stent comprising a hemostatic agent on the external surface of the stent and an anticoagulant on the internal surface of the stent, as taught by Alt et al., with the stent of Datta et al., in order to enable different beneficial actions to occur at different surfaces of the stent.

Jernberg discloses a urethral prosthesis (see claim 1) comprising an anticoagulant (e.g., heparin) on an internal surface (see column 5, lines 30-36; column 6, lines 13-16) in order to prevent formation of blood clots at the implantation site (see column 2, lines 28-31). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have

combined the teaching of a stent comprising a an anticoagulant on an internal surface of the stent, as taught by Jernberg, with the stent of Datta et al., in order to prevent formation of blood clots at the implantation site.

With regards to the specific anticoagulants and hemostatic agents, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have used any of the listed anticoagulants and hemostatic agents with the stent of Datta et al., since it has been held to be within the general skill of a worker in the art to select a know material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 7, 9-12, 14, 15, and 19-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Devonec (US 5,766,209 A; cited in Applicant's IDS) in view of Donovan et al. (5,833,651 A; cited in Applicant's IDS), Alt et al. (US 5,788,979; cited in Applicant's IDS), or Jernberg (US 5,290,271 A).

Referring to Figures 1, 2, and 13, Devonec '209 discloses a prostatic stent comprising:

(i) A first segment (**first interpretation:** tubular segment 9; **second interpretation:** tubular segment 9 + proximal portion of sleeve 10) including an external surface, and internal surface, a

proximal portion, a distal end, a lumen defined by the internal surface and extending within the first segment, and a plurality of openings (**first interpretation:** perforations 9c, as shown in Figure 6; **second interpretation:** perforations 51, as shown in Figure 13; **third interpretation:** perforations on the proximal portion of sleeve 10, as shown in Figures 5b and 5c), the proximal portion including at least one opening (Figure 1: proximal opening on proximal end) in communication with the lumen;

(ii) A second segment (11) including an external surface, and internal surface, a proximal end, a distal end, a lumen defined by the internal surface and extending within the second segment; and **(iii)** A connecting segment (10) disposed between the first and second segments and coupling together the first and second segments. Devonec '209 clearly discloses said connecting segment as either a single wire, a plurality of wires, or a sleeve (see column 2, lines 40-50). Devonec also discloses that each of the tubular segments 9 and 11, and connecting segment, "can be coated on its outer surface with a therapeutic substance" (see column 6, lines 4-5). Devonec further discloses a method of positioning the claimed structure of the stent within the urinary system (see column 6, lines 24-67; column 7, lines 1-43). Openings 9c (shown in Figure 6) communicate with the internal lumen of the stent, and are capable of conveying at least one agent from the lumen to the external surface of the stent.

Although Devonec discloses that each of the tubular segments 9 and 11 "can be coated on its outer surface with a therapeutic substance" (see column 6, lines 4-5), he did not disclose the use of a hemostatic agent on the external surface of the tubular elements and an anticoagulant on the internal surface of the tubular elements. However, this is already known in the art. For example:

Donovan et al. disclose a stent (see column 13, lines 66-67; column 14, lines 1-9) comprising a hemostatic agent (i.e., fibrin) on the external surface of the stent (see column 5, lines 61-67; column 8, lines 13-17) and an anticoagulant (i.e., heparin) on the internal surface of the stent (see column 15, lines 15-26) in order to convey a therapeutic action(s) in the area (i.e., urinary tract) to be treated (see entire document), and to enable different beneficial actions to occur at different surfaces of the stent.. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of a stent comprising a hemostatic agent on the external surface of the stent and an anticoagulant on the internal surface of the stent, as taught by Donovan et al., with the stent of Devonec '209, in order to convey a therapeutic action(s) in the area to be treated, and to enable different beneficial actions to occur at different surfaces of the stent.

Alt et al. disclose a stent comprising a polymerizable hemostatic agent on an external surface, and an anticoagulant on an internal surface (see column 6, lines 8-13; see Examples) in order to enable different beneficial actions to occur at different surfaces of the stent (see column 6, lines 5-16). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of a stent comprising a hemostatic agent on the external surface of the stent and an anticoagulant on the internal surface of the stent, as taught by Alt et al., with the stent of Devonec '209, in order to enable different beneficial actions to occur at different surfaces of the stent.

Jernberg discloses a urethral prosthesis (see claim 1) comprising an anticoagulant (e.g., heparin) on an internal surface (see column 5, lines 30-36; column 6, lines 13-16) in order to prevent formation of blood clots at the implantation site (see column 2, lines 28-31). It would

have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of a stent comprising a an anticoagulant on an internal surface of the stent, as taught by Jernberg, with the stent of Devonec '209, in order to prevent formation of blood clots at the implantation site.

With regards to the specific anticoagulants and hemostatic agents, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have used any of the listed anticoagulants and hemostatic agents with the stent of Devonec '209, since it has been held to be within the general skill of a worker in the art to select a know material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

As noted by the United States Supreme Court, if a person of ordinary skill can implement a predictable variation, § 103 likely bars its patentability. For the same reason, if a technique has been used to improve one device, and a person of ordinary skill would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill. *KSR*, 127 S. Ct. at 1740. "When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product is not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show it was obvious under 35 U.S.C. 103." *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1742, 82USPQ2d 1385, 1396 (2007).

Response to Arguments

9. Applicant's arguments filed February 14, 2008 have been fully considered but they are not persuasive. Applicant's arguments have been adequately addressed in the rejections (above).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:00 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Javier G. Blanco/ Examiner, Art Unit 3774

/Dave Willse/

Primary Examiner, Art Unit 3738